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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,292	12/02/2003	Shinichi Tsuzaki	JCLA12308	5325

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J C PATENTS, INC.
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EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,292

Applicant(s)

TSUZAKI ET AL.

Examiner

S. B. McCormick-Ewoldt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 5, 2005 has been entered.

Claims Pending

Applicant has cancelled claims 3-6 and added new claims 7-11. Claims 1-2 and 7-11 will be examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 9 rejected under 35 U.S.C. 102(b) as being anticipated by Mizutani (JP-10298175).

Mizutani (JP-10298175) expressly teaches using soybean hypocotyls to obtain an extraction that contains water-soluble isoflavones, with the isoflavones content is 20% and the insolubles are eliminated by centrifugation. In the extraction of the isoflavones, the pH ranges from 2 to 8 and temperatures ranges from 5°C to 40°C (whole document). The isoflavones extracted by Mizutani meet the limitations of claim 1 as the method comprises extracting isoflavones from soybean hypocotyls and thus anticipates the claimed invention.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani (JP-10298175), Bryan *et al.* (US 5,994,508) and Obata *et al.* (US 6,444,239).

Mizutani (JP-10298175) discloses using soybean hypocotyls to obtain an extraction that contains water-soluble isoflavones, with the isoflavones content is 20% and the insolubles are eliminated by centrifugation. In the extraction of the isoflavones, the pH ranges from 2 to 8 and temperatures ranges from 5°C to 40°C (whole document). Mizutani does not disclose extracting without protease.

Bryan *et al.* (US 5,994,508) discloses using a process of extracting soybean isoflavones with the temperature typically from about 30°F to about 90°F (i.e. -1°C to 32°C) (column 5, lines 30-35, 53-57 and claims 1, 3-4, 6). Bryan *et al.* does not specifically teach the pH or amounts of isoflavones, crude protein or lipid content of the total solid content of the soybean extract liquid.

Obata *et al.* (US 6,444,239) disclose that the isoflavone precipitate can be freeze-dried (see Example 2).

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The references taken together disclose a method for the extraction isoflavones from soybean hypocotyls. A person of ordinary skill in the art would be motivated to combine the teachings of Mizutani, Bryan and Obata because Mizutani discloses the pH ranges and temperature of extracting soybean isoflavones from soybean hypocotyls and Bryan discloses extracting isoflavones without the use of a protease and Obata discloses the isoflavone precipitate can be freeze-dried. Based on this reasonable expectation of success one of ordinary skill in the art would have been motivated to make modifications to Mizutani, Bryan and Obata.

Although none of the references disclose the amounts of protein or lipid content, one of ordinary skill in the art would have been motivated to vary the pH level and temperature as the level of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to vary the pH and temperature levels to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient levels would have been obvious at the time of Applicant's invention.

One of ordinary skill in the art would have been motivated to vary the pH level and temperature as the level of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to vary the pH and temperature levels to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient levels would have been obvious at the time of Applicant's invention.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

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the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Summary

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Terry McKelvey, can be reached on (571) 272-0775. The official fax number for the group is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe

11-22-05

**SUSAN COE
PRIMARY EXAMINER**